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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* JOHN THOMAS ALLEN, GEORGE MICHAEL SULLIVAN, and  
COLIN BRIAN WILLIAMS

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Appeal 2009-003787  
Application 09/912,576  
Technology Center 1700

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Decided: March 31, 2010

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Before EDWARD C. KIMLIN, TERRY J. OWENS, and  
PETER F. KRATZ, *Administrative Patent Judges*.

KRATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 3, 4, 6, 7, and 9-52. We have jurisdiction pursuant to 35 U.S.C. § 6.

Appellants' claimed invention is directed to a method and apparatus for irradiating articles, such as food, drugs, and/or medical items, wherein a closed container housing articles in a predetermined configuration and a radiation absorbing fixture are arranged in a removable manner and moved or constructed to move together, e.g., in a traverse direction, through radiation energy emanating from a source. The fixture is arranged between the radiation source and external to the closed container and articles placed within the closed container during the movement through the radiation energy in a manner such that the fixture can help maintain radiation dosage received at different positions of each contained article within desired minimum and maximum limits.

Claims 1, 25, 32, 35 are illustrative and reproduced below:

1. A method of irradiating an article from a radiation source where the article absorbs the radiation at different positions in the article in accordance with irregularities in the characteristics of the article at the different positions, including the steps of:

providing the radiation from the source in a particular direction,

providing a closed container including the articles,

absorbing the radiation energy passing from the source to the articles at the different positions in the closed container in accordance with the irregularities in the characteristic of the article at the different positions to maintain the radiation dose at the different positions in the article within particular minimum and maximum limits, and

moving the closed container past the radiation from the source in a direction transverse to the particular direction,

wherein the absorption is provided by a fixture having characteristics for absorbing the radiation energy at the different positions depending upon the irregularities in the characteristics of the article at the different positions,

wherein the article is disposed within the closed container and the fixture is disposed external to the closed container.

25. A method of irradiating articles from a radiation source where the articles absorb radiation by a dosage depending upon the characteristics of the articles and where the articles have different absorption characteristics to the radiation at progressive positions in the articles, the absorption of the radiation in the articles being dependent upon the at least one of the composition and geometric shape and density of the articles, including the steps of:

providing the radiation from the source in a particular direction,

providing a closed container including the articles,

providing a fixture having a composition with characteristics of absorbing the radiation corresponding to the absorption of the radiation by the at least one of the composition density and geometrical shape of the articles and having at progressive positions absorption characteristics compensating the absorption characteristics of the articles at the progressive positions,

disposing the fixture outside of the closed container to provide the at least one of a substantially constant geometric shape, density and composition between the combination of the articles and the fixture at progressive positions on the articles, and

moving the combination of the closed container and the fixture past the radiation from the source in a direction substantially perpendicular to the radiation from the source.

32. In combination,

a radiation source for providing radiation in a particular direction,

a closed container including a plurality of articles each having irregularities in its characteristics at different positions in the article where the irregularities in its characteristics affect the radiation dosage absorbed by the article at the different positions from the radiation source,

a fixture having irregularities in its characteristics to compensate for the irregularities in the characteristics of the articles, the fixture being disposed outside of the closed container, and

a conveyor for moving the closed container and the fixture in a direction substantially perpendicular to the particular direction.

35. In a combination as set forth in claim 32 wherein the closed container is moved past the radiation from the source at a substantially constant speed within particular limits

The Examiner relies on the following prior art references as evidence in rejecting the appealed claims:

Peck	5,590,602	Jan. 7, 1997
Ichihara	6,030,554	Feb. 29, 2000
Doi <sup>1</sup>	JP 2000-312708	Nov. 14, 2000

The Examiner maintains the following grounds of rejection.

Claims 1, 3, 4, 6, 7, 9-15, 17-35, and 37-52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Doi in view of Ichihara. Claims 16 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Doi in view of Ichihara and Peck.

We affirm the stated rejections for substantially the reasons set forth by the Examiner in the Answer (Ans. 4-10). We offer the following for emphasis.

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<sup>1</sup> Our references to Doi are to the English language translation of record.

Rejection over Doi in view of Ichihara

Appellants present separate arguments for dependent claims 6, 12, 15, and 35 as a group; but, Appellants do not separately argue rejected claims 1, 3, 4, 7, 9-11, 13, 14, and 17-34.<sup>2</sup> Consequently, we select claims 32 and 35, as representative claims on which we shall primarily focus in deciding this appeal.

The Examiner has correctly determined that Doi teaches or suggests a method and apparatus for sterilizing items, such as food products, drugs, medical equipment, etc., via uniform irradiation using a radiation source; a radiation regulator (fixture) (10), and a conveyor (Ans. 4-6; Doi; paras. 0001, 0004- 0008, 0026-0029, Figs 6A and 6B). In this regard, Doi teaches radiation dose distribution can be controlled by interposing a dose regulator (fixture) 10 between an item to be irradiated (dialyzer 15) and a radiation source while both the fixture 10 and item to be irradiated 15 are transported via a conveyor past a radiation beam to assist (para. 0026, Fig. 6). The Examiner recognizes that Doi does not disclose a separate closed container for housing a plurality of items to be irradiated in addition to the fixture (radiation regulator) required by representative claim 32.

The Examiner turns to Ichihara for teaching packaging items (lenses) prior to irradiation sterilization so as to minimize or inhibit recontamination of the items after sterilization (terminal sterilization) as may happen if handling and packaging non-sealed irradiated items takes place after sterilization (Ans. 5; Ichihara, Abs., col. 2, ll. 32-40; col. 6, ll. 30-57).

The Examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of the invention to package the articles

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<sup>2</sup> Merely stating what a particular claim requires does not amount to a separate argument for the patentability of that claim.

(dialyzers) of Doi prior to sterilization to prevent subsequent contamination in light of the teachings of Ichihara and that, in effecting such a modification, one of ordinary skill in the art would have obviously repositioned the radiation regulators/ fixtures of Doi such that they were located external to such added packaging (closed containers) (Ans. 5).

Appellants contend that neither reference discloses a separate closed container for holding multiple articles in a predetermined configuration and that the combination of Doi with Ishihara would not have taught disposing a fixture (radiation regulator) external to a closed container (packaging) that holds a plurality of articles (Br. 14-15).

Consequently, a principal issue before us is:

Have Appellants identified error in the Examiner's determination that the combined teachings of Doi and Ichihara would have suggested packaging articles of Doi prior to irradiation sterilization and, consequently, would have led one of ordinary skill in the art to modify and locate dose regulator (fixtures) of Doi at positions external to package(s) holding items to be irradiated in a predetermined manner in the method and/or apparatus of Doi?

We answer this question in the negative.

## DISCUSSION

In addition to findings of fact set forth elsewhere in this Opinion and in the Examiner's Answer, we note that Ishihara teaches or suggests that a closed container, such as a box, can accommodate more than one item (lens) for its irradiation while being packaged therein (col. 6, ll. 48-50).

Moreover, Appellants acknowledge that it was known to use a conveyor for transporting an article having positional irregularities in its

characteristics, such as shape, and a movable fixture past a radiation source to provide for irradiation of the article with different dosages and/or intensities at different positions of the article within particular minimum and maximum limits (Spec. 9; Figs 1-4). This acknowledgement correlates with the teachings of Doi (see; e.g., Doi, paras. 0026-0029; Fig. 6).

In addition to a system including a conveyor and a radiation source, representative claim 32 calls for a closed container housing several articles and a fixture, located externally of the container, in combination therewith.

Appellants do not dispute that Doi discloses a system including a conveyor for articles to be irradiated, a radiation source, and an appropriately configured dose regulator (fixture) 10 located externally of an article to be irradiated (15) (see generally Br; Doi, paras. 0026, 0028 and 0029, Figs. 6A and 6B). Nor do Appellants contend that Ichihara fails to teach or suggest the use of a closed container for packaging items (lenses) before they are sterilized via irradiation so as to prevent recontamination of the sterilized items.

While we agree with Appellants that Doi does not further describe packaging items prior to irradiation, the combination of Ichihara and Doi would have suggested such an option to an ordinarily skilled artisan to protect the irradiated items from recontamination, as reasonably asserted by the Examiner. On this record, Appellants have not persuaded us otherwise by mere attorney argument to the contrary. One of ordinary skill in the art would have readily recognized the option of locating a properly configured dose regulator of Doi external to such a pre-packaged item as being an appropriate option. In this regard, if the dose regulator were otherwise located, that is, inside the package, the advantages to be gained by pre-packaging the item to be radiated would be vitiated.



Moreover, we disagree with Appellants assertion that only a single item per package would have, at best, been suggested by a combination of Doi and Ichihara (Br. 15). Rather, one of ordinary skill in the art would have recognized that employing a closed container that accommodates more than one article, as suggested by Ichihara, in a predetermined configuration therein (such as a box holding two items in pre-determined positions therein) would have been a readily available and recognizable packaging option for use in Doi.

After all, in considering the question of the obviousness of the claimed invention in view of the prior art relied upon, we are guided by the basic principle that the question under 35 U.S.C. § 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made. *See Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807 (Fed. Cir.) and *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). That is, the question of obviousness cannot be approached on the basis than an artisan having ordinary skill would have known only what they read in the references, because such artisan is presumed to know something about the art apart from what the references disclose. *See In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962). Moreover, it is not necessary that suggestion or motivation be found within the four corners of the references themselves; a conclusion of obviousness may be made from common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *See In re Bozek*, 416 F.2d 1385 (CCPA 1969). Further, in an obviousness assessment, skill is presumed on the part of the artisan, rather than the lack thereof. *In re Sovish*, 769 F.2d 738 (Fed. Cir. 1985).

Concerning representative claim 35 (separately argued dependent claims 6, 12, 15 and 35), Appellants argue that the applied references do not teach or suggest moving the articles past the radiation source at a constant speed (Br. 16-17). This argument is not persuasive of error in the Examiner's obviousness determination of representative claim 35 because Doi teaches or suggests that the items can be sterilized in route while being conveyed by a conveyor belt past electron beam irradiation sources (para. 0026). Doi teaches that a uniform dose of irradiation can be delivered (0026 and 0029). Appellants have not directly confronted and convincingly explained why the aforementioned teachings of Doi do not reasonably suggest to one of ordinary skill in the art a uniform or constant conveyance speed of the items to be irradiated by the conveyor belt.

Given the above, Appellants have not persuaded us why the Examiner errs in maintaining the first stated obviousness rejection.

#### Rejection over Doi in view of Ichihara and Peck

Concerning the Examiner's obviousness rejection of claims 16 and 36 over the combined teachings of Doi, Ichihara, and Peck, we select claim 36 as the representative claim for these commonly argued claims. Appellants contend that dependent claim 36 is patentable for the same reasons that independent claim 32 is patentable (Br. 18). Appellants do not otherwise contest the Examiner's additional application of Peck to the subject matter added by representative claim 36. Because we have not found Appellants' arguments with respect to claim 32 persuasive for reasons set forth above, it follows that we likewise find these arguments unpersuasive with respect to representative claim 36.

ORDER

The Examiner's decision to reject the appealed claims is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

tc

PETER K HAHN  
LUCE, FORWARD, HAMILTON, SCRIPPS, LLP.  
600 WEST BROADWAY  
SUITE 2600  
SAN DIEGO, CA 92101